press release

Victoza® significantly reduced the risk of major cardiovascular events and death in adults with type 2 diabetes in the LEADER trial

New Orleans, US, 13 June 2016 – Novo Nordisk today announced that Victoza® (liraglutide) significantly reduced the risk of the composite primary endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (heart attack) or non-fatal stroke by 13% vs placebo (95% confidence interval [CI]: 0.78; 0.97, p=0.01), when added to standard of care in 9,340 adults with type 2 diabetes at high CV risk. The main results of the LEADER trial were presented today at the American Diabetes Association's 76th Scientific Sessions (ADA 2016) and also published in the *New England Journal of Medicine*.[1, 2] Victoza® is the only approved GLP-1 receptor agonist to demonstrate a superior reduction of major CV events vs placebo, both on top of standard of care, in a cardiovascular outcomes trial.

There was a significant 22% reduction in cardiovascular death with Victoza® treatment vs placebo (95% CI: 0.66; 0.93, p=0.007) and reductions in non-fatal myocardial infarction (HR=0.88, 95% CI: 0.75; 1.03, p=0.11) and non-fatal stroke (HR=0.89, 95% CI: 0.72; 1.11, p=0.30).[1, 2]

"These findings are exciting, as it demonstrates that Victoza® can improve outcomes beyond glucose reduction and weight loss by helping to avoid cardiovascular complications and death in people with type 2 diabetes," said Dr John Buse, chairman of the LEADER Steering Committee and chief of Endocrinology and director of the Diabetes Care Centre at the University of North Carolina School of Medicine. "Type 2 diabetes treatments that can also reduce cardiovascular risk are important since cardiovascular disease is the leading cause of death worldwide in this patient population."

All-cause death was significantly reduced by 15% with Victoza® compared to placebo (95% CI: 0.74; 0.97, p=0.02). The expanded CV endpoint was significantly reduced by 12% with Victoza® compared to placebo (95% CI: 0.81; 0.96, p=0.005). The expanded CV endpoint included the three components of the primary endpoint in addition to

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unstable angina leading to hospitalisation, coronary revascularisation and hospitalisation for heart failure.[1, 2]

From a mean baseline of 8.7% (both groups), there was a greater reduction in HbA_{1c} with Victoza® vs placebo, both on top of standard of care, at three years (estimated treatment difference [ETD]: -0.40%, 95% CI: -0.45; -0.34). Weight loss was also sustained over three years with Victoza® treatment vs placebo (ETD: -2.3 kg, 95% CI: -2.5; -2.0). Mean baseline weight was 91.9 kg and 91.6 kg, respectively.[1, 2]

"We are very excited by the LEADER trial results that demonstrate a significant reduction in major cardiovascular events among type 2 diabetes patients treated with Victoza®, including all-cause death," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "For us, this marks the beginning of a new era where our R&D focus will go beyond glucose control."

The proportion of adults experiencing adverse events was similar between the Victoza® and the placebo groups (62.3% vs 60.8%, respectively). The most common adverse events leading to the discontinuation of Victoza® were gastrointestinal events. The incidence of pancreatitis was non-significantly lower in the Victoza® group than in the placebo group.[1, 2]

About LEADER
LEADER was a multicentre, international, randomised, double-blind, placebo-controlled trial investigating the long-term effects of Victoza® (liraglutide up to 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of major cardiovascular events. Standard of care was comprised of lifestyle modifications, glucose-lowering treatments and cardiovascular medications.

LEADER was initiated in September 2010 and randomised 9,340 people with type 2 diabetes from 32 countries that were followed for 3.5–5 years. The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.[2]

About Victoza®
Victoza® (liraglutide) is a human glucagon-like peptide-1 (GLP-1) analogue with an amino acid sequence 97% similar to endogenous human GLP-1.

Victoza® was launched in the EU in 2009 and is commercially available in more than 85 countries, treating more than 1 million people with type 2 diabetes globally.[3, 4] In Europe, Victoza® is indicated for the treatment of adults with type 2 diabetes to achieve glycaemic control as monotherapy, when metformin is considered inappropriate, and in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.[3] In the US, Victoza® was approved in 2010 as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes.[5]

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About Novo Nordisk

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 41,600 people in 75 countries and markets its products in more than 180 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

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